REMARKS

Claims 1-21 were presented with the instant application was filed. Subsequently, in response to a restriction requirement, Applicants elected to prosecute claims 1-15 of Group I, and cancelled Claims 16-21 without prejudice to their future prosecution.

Claims 7 and 15 have been cancelled in the present amendment.

Claims 1-6 and 8-14 are pending.

In the Office Action dated July 1, 2005, the examiner has:

I) rejected Claims 1-15 under 35 U.S.C 112, first paragraph, as allegedly containing subject matter which was not described in the specification;

II) rejected Claims 1-15 under 35 U.S.C. 102(e) as allegedly being anticipated by Straus (U.S. Publication No. 2002/0086289 A1) as evidenced by DeRisi et al (Science 278:680-686, 1997);

III) rejected Claims 1-5, 7-13, and 15 under 35 U.S.C 103(a) as allegedly being unpatentable over Kuiper et al. (Current Opinion in Biotechnology, 1999, 10:511-516) and Greisen et al., (J. Clin. Microbial. 1994, vol. 32, pp. 335-351); and

IV) rejected claims 6 and 14 under 35 U.S.C 103(a) as allegedly being unpatentable over Kuiper et al. (Current Opinion in Biotechnology, 1999, 10:511-516) and Greisen et al., (J. Clin. Microbial. 1994, vol. 32, pp. 335-351) in further view of Arfin et al., (J. Biol. Chem. 2000, vol. 275, pp. 29672-29684).

We disagree.

I) The Claim Language is Supported by the Specification

The Examiner has rejected Claims 1-15 under 35 U.S.C 112, first paragraph, as containing subject matter which was not described in the specification because recited "in a single step" and "the specification does not teach a single step to produce a hybridization pattern." We disagree. A "single step" hybridization embodiment is described. Nonetheless, in order to further prosecution, and in no way acquiescing to the Examiner rejection, expressly reserving the right to prosecute the same or similar claims, Applicants have removed the "co"-hybridization and "in a single step" limitations in Claim 1 and 9.

II. The Claims are Novel

The Examiner has rejected Claims 1-15 under 35 U.S.C. 102(e) as allegedly being anticipated by Straus (U.S. Publication No. 2002/0086289 A1, hereinafter "Straus") as evidenced by DeRisi et al (Science 278:680-686, 1997, hereinafter DeRisi). We disagree for the reasons previously presented and those below.

First, the Examiner is not applying the proper standard for anticipation. A 35 U.S.C. 102(e) rejection cannot be based on the combination of two references, i.e., a 102(e) rejection cannot be sustained by reference to other references. Moreover, the DeRisi disclosure is not incorporated by reference in Straus. "[A]n incorporation by reference must be set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words 'incorporat(e)' and 'reference' (*e.g.*, 'incorporate by reference'); and (2) Clearly identify the referenced patent, application, or publication." CFR 1.57(b). Straus does not expressly use the term "incorporate" with regard to the DeRisi reference. Even if Straus did incorporate DeRisi, which it does not, the combined references do not anticipate the pending claims because the Examiner has not cited Straus and DeRisi as containing every element of the claimed invention. Nonetheless, in order to further prosecution, and in no way acquiescing to the Examiner rejection, expressly reserving the right to prosecute the same or similar claims, Applicants have cancelled claims 8 and 15, and amended the claims 1 and 9 to recite that: (1) **both target** DNA is "labeled with a fluorescent dye" and **reference** DNA is "labeled

with a fluorescent dye" and (2) calculating the **hybridized** target and reference labeled "fluorescent dyes" signals.

Neither Straus nor DeRisi disclose hybridizing labeled fluorescent reference DNA **from at least four strains of reference bacteria** and hybridizing fluorescently labeled target DNA, wherein reference bacteria are members of the group consisting of said plurality of bacterial species arrayed on a solid support. In the most recent office action, the Examiner alleges that Straus teaches detection sequences arrayed on a solid support and the combination of positive and negative control probes with test sample for the preparation of fingerprints with which test sample patterns may be compared. Office Action page 4, lines 8-12. Thus, the Examiner argues that "Straus does teach the simultaneous hybridization of labeled target and reference DNA. . ." Office action page 5, lines 13-15. However, the Examiner does not explain why. Even assuming the Examiner considers the "control probes" of Straus to be "reference DNA" of the current invention, Straus does not teach the limitation that the reference DNA come **from at least four strains of reference bacteria**. Thus, neither Straus nor DeRisi teach every element of the pending claims and this rejection should be withdrawn. Merely asserting that "reference" DNA is disclosed in DeRisi is not sufficient, given the express claim language.

III) The Claims are Not Obvious in Light of Kuiper and Greisen

The Examiner has rejected Claims 1-5, 7-13, and 15 under 35 U.S.C 103(a) as allegedly being unpatentable over Kuiper et al. (Current Opinion in Biotechnology, 1999, 10:511-516) and Greisen et al., (J. Clin. Microbial. 1994, vol. 32, pp. 335-351). We disagree for the reasons previously provided, and for all the reasons stated below. In order to establish prima facie case of obviousness the cited prior art must teach or suggest all claim limitations. The Examiner has not taught every element of the claimed invention because neither Kuiper nor Greisen disclose hybridizing labeled fluorescent reference DNA from at least four strains of reference bacteria and hybridizing fluorescently labeled target DNA, wherein reference bacteria are members of the group consisting of said plurality of bacterial species arrayed on a solid support.

The Examiner alleges that the invention is obvious because Kuiper et al. suggests

using different multiplexing labeled probes for combining several different cDNA samples for the possibility of multiplexing. See Examiners Answer page 7, lines 8 –13 and page 9, lines 7 and 8. The paragraph in Kuiper that the Examiner refers to states that

> Fluorescently labeled cDNA is **used for hybridization to the DNA arrays** and the signals are detected by confocal laser scanning. The wild-type and mutant-strain cDNAs can be differentially labeled and used in one combined sample for hybridization, providing the attractive possibility of multiplexing. Kuiper et al., 512, col. 2, lines 9-14. (emphasis added)

If anything, this suggests that wild-type and mutant strain DNA is labeled. However, this does not teach hybridizing labeled fluorescent reference DNA from at least four strains of reference bacteria and hybridizing fluorescently labeled target DNA, wherein reference bacteria are members of the group consisting of said plurality of bacterial species arrayed on a solid support. In addition, Gerisen does not provide this missing teachings.

IV) The Claims are Not Obvious in Light of Kuiper and Greisen in view of Arfin

The Examiner has rejected claims 6 and 14 under 35 U.S.C 103(a) as allegedly being unpatentable over Kuiper et al. (Current Opinion in Biotechnology, 1999, 10:511-516) and Greisen et al., (J. Clin. Microbial. 1994, vol. 32, pp. 335-351) in further view of Arfin et al., (J. Biol. Chem. 2000, vol. 275, pp. 29672-29684). We disagree for the reasons previously provided and for all the reasons stated above. The Applicants believe that the Examiner improperly combined the Kuiper and Greisen references and, therefore, that the obviousness rejection of these claims is unsupported by the references and, therefore, improper. Arfin is not particularly relevant because it merely provides an example of methods that could be used by the Applicant and does not supplement the missing teachings of Kuiper and Greisen.

Conclusion

Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that these grounds for rejection be withdrawn and the amendments entered and a timely notice of allowance issued for the reasons set forth above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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Peter G. Carroll
Registration No. 32,837

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
617.984.0616